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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/501,566

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Yumiko Uno

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EXAMINER

LOCKARD, JON MCCLELLAND

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

11/06/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/501,566	Applicant(s) UNO ET AL.	
	Examiner JON M. LOCKARD	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20 and 116-118 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20 and 116-118 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 July 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Amendment filed 28 July 2008 has been entered in full. Claim 20 has been amended, claims 1-19 and 21-115 have been cancelled without prejudice, and claims 116-118 have been added. Newly added claims 116-118 will be examined as they fit under the rubric of the elected invention. Therefore, claims 20 and 116-118 are pending and the subject of this Office Action.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections and/or Rejections

3. The objections to the Drawings as set forth at pg 4 of the previous Office Action (mailed 19 February 2008) are withdrawn in view of Applicant's amendment of the Specification and submission of replacement Drawings (filed 28 July 2008).
4. The objections to the Specification as set forth at pg 5 of the previous Office action (mailed 28 July 2008) are withdrawn in view of Applicant's cancellation of said claims (filed 28 July 2008).
5. The objection to claims 1 and 2 as set forth at pg 5 of the previous Office action (mailed 28 July 2008) is moot in view of Applicant's amendments to the Specification (filed 28 July 2008).

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6. The rejection of claims 1, 2, and 4 under 35 U.S.C. § 101 as set forth at pg 6 of the previous Office action (mailed 28 July 2008) is moot in view of Applicant's cancellation of said claims (filed 28 July 2008).

7. The rejection of claims 1, 2, 4, 11, and 20 under 35 U.S.C. § 112, 1st Paragraph (Scope of Enablement and Written Description) as set forth at pg 6-12 of the previous Office action (mailed 28 July 2008) is withdrawn in view of Applicant's cancellation of claims 1, 2, 4, and 20, and amendment of claim 11 which now recites a specific protein (filed 28 July 2008).

8. The rejections applied to claims 1, 2, 4, 11, and 20 under 35 U.S.C. § 112, 2nd Paragraph as set forth at pg 13 of the previous Office Action (mailed 28 July 2008) are withdrawn in view of Applicant's cancellation of claims 1, 2, 4, and 20, and amendment of claim 11 which no longer recites "the partial peptide" (filed 28 July 2008).

9. The rejections applied to claims 1, 2, 4, and 20 under 35 U.S.C. § 102(b) as being anticipated by Dawson (U.S. Pat. No. 5,589,358) as set forth at pg 14-15 of the previous Office action (mailed 28 July 2008) and under 35 U.S.C. § 102(e) as being anticipated by Wilganowski et al. (US 2002/0164627) as set forth at pg 15 of the previous Office action (mailed 28 July 2008) are withdrawn in view of Applicant's cancellation of claims 1, 2, and 4, and amendment of claim 20 which now recites a kit comprising a specific protein and a substrate of the protein (filed 28 July 2008).

New Objections and/or Rejections

Claim Rejections - 35 USC § 112, 1st Paragraph (New Matter)

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 20 and 116-118 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

12. Claim 20 recites the limitation “and a substrate of the protein”. The claims also recite wherein the substrate of the protein is a steroid, wherein the steroid hormone is selected from the group consisting of estrogen and androgen, and wherein the estrogen is estrone or metabolites thereof and the androgen is dehydroepiandrosterone or metabolites thereof. After extensive review, the Examiner is unable to find, in the Specification as originally filed, support for this newly added limitation of “a substrate of the protein” within the context of a kit comprising the protein of SEQ ID NO:1 recited in the claims. This newly added limitation is not expressly asserted, nor does it flow naturally from the Specification as originally filed. The discussion at pg 84, lines 13-16 of Specification (filed 15 July 2004) as asserted by Applicant at pg 6 of the response (filed 28 July 2008) is noted; however the disclosure is limited to a substrate of the protein in the context of *a cell* that expresses the protein.

Claim Rejections - 35 USC § 112, 1st Paragraph (Enablement)

13. Claims 20 and 116-118 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

14. The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is “undue” include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

15. Claim 20 recites a kit for screening a compound or its salt that promotes the activity of a protein comprising the amino acid sequence of SEQ ID NO:1 or its salt which comprises the protein or its salt and a substrate of the protein. The claims also recite wherein the substrate of the protein is a steroid, wherein the steroid hormone is selected from the group consisting of estrogen and androgen, and wherein the estrogen is estrone or metabolites thereof and the androgen is dehydroepiandrosterone or metabolites thereof. However, the instant specification fails to teach how to use a kit comprising said components to screen for compounds that promotes or inhibits the activity of a protein comprising the amino acid sequence of SEQ ID NO:1, thus requiring undue experimentation of one skilled in the art to use the claimed invention with a reasonable expectation of success.

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16. There are no working examples, in either the instant specification or the art of record, of utilizing a transporter protein and a substrate of the protein to screen for compounds which promotes or inhibits the activity of the transporter protein. This is because transporter proteins are not known to function outside of the context of a biological membrane. Since neither the art of record nor the instant specification discloses how to utilize a transporter protein and a substrate of the protein to screen for compounds which promotes or inhibits the activity of the transporter protein outside of the context of the transporter protein comprised in a cell, a skilled artisan certainly can not use the transporter polypeptide of SEQ ID NO:1 and a substrate of this protein in this capacity without first inventing a process of inserting the protein into a cell or membrane in its proper orientation.

17. A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentech, Inc. v. Novo Nordisk*, 42 USPQ 2d 100, (CAFC 1997), the court held that: “[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable”, and that “[t]ossing out the mere germ of an idea does not constitute enabling disclosure”. The court further stated that “when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art”, “[I]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement”.

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18. Thus, in view of the lack of guidance and the total absence of working examples, the instant specification is not found to be enabling for a kit for screening a compound or its salt that promotes the activity of a protein comprising the amino acid sequence of SEQ ID NO:1 or its salt, which comprises the protein or its salt and a substrate of the protein. It would require undue experimentation and making a substantial inventive contribution for the skilled artisan to discover how to use the Applicants' invention as currently claimed.

Summary

19. No claim is allowed.

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 7:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Manjunath N. Rao**, can be reached on **(571) 272-0939**.

The fax number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

/J. M. L./
Jon M. Lockard, Ph.D.
Examiner, Art Unit 1647
October 30, 2008

/Christine J Saoud/
Primary Examiner, Art Unit 1647